In the United States Court of Federal Claims

ALA MOHAMAD,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

No. 16-1075
(Filed Under Seal: November 12, 2024)
(Reissued Publicly: December 2, 2024)

Richard Gage, Richard Gage, P.C., Cheyenne, Wyoming, for Petitioner.

Voris E. Johnson, *Jr.*, Assistant Director, *Julia M. Collison*, Assistant Director, *Heather L. Pearlman*, Deputy Director, *C. Salvatore D'Alessio*, Director, Torts Branch, *Brian M. Boynton*, Principal Deputy Assistant Attorney General, Civil Division, United States Department of Justice, Washington, D.C., for Respondent.

OPINION AND ORDER[1]

HADJI, *Judge*.

Respondent, the Secretary of Health and Human Services, seeks review of Special Master Christian J. Moran's entitlement ruling and award of compensation in favor of Petitioner, who began suffering from Guillain-Barré Syndrome (GBS) shortly after receiving a tetanus-diphtheria-acellular pertussis (Tdap) vaccine in September 2015. ECF 258. For the reasons stated below, Respondent's Motion for Review is **DENIED**, and the Special Master's Decision is **SUSTAINED**.

BACKGROUND

I. Petitioner's Medical History

As the underlying facts set forth in Petitioner's medical records are not in dispute, the Court's recitation of facts draws largely from the Special Master's entitlement ruling. *See* ECF 259 at 2; ECF 261 at 8.

[1] This Opinion was issued under seal on November 12, 2024. The parties were directed to propose redactions by November 26, 2024. No proposed redactions were received. The Court hereby publicly releases the Opinion and Order in full.

On September 18, 2015, Petitioner received a Tdap vaccine during a routine physical. ECF 150 at 2. Less than two weeks later, he visited a medical facility complaining of numbness in his hands, feet, and lower back. *Id*. The treating physician diagnosed Petitioner with hyperventilation syndrome. *Id*.

The next morning, Petitioner fell in his home and was taken to the emergency room where he again complained of numbness. *Id*. The emergency room doctor diagnosed him with paresthesias of both hands and feet. *Id*. at 3. Petitioner fell again the next morning. *Id*. Following tests, including MRIs and a lumbar puncture, Petitioner was diagnosed with GBS and hospitalized for almost the entirety of October 2015. *Id*. at 3-4. During his stay, two doctors concluded that Petitioner's GBS was "likely triggered" by his Tdap vaccination. *Id*. at 3. Petitioner's internist theorized that Petitioner could have nephritis and noted that his review of literature indicated that glomerulonephritis has been associated with GBS. *Id*. at 3-4. Petitioner's internist sought a consult from the nephrology service, which suggested that a kidney biopsy might be needed to reach a definitive diagnosis. *Id*. at 4. Due to a necessary GBS treatment and the state of Petitioner's kidney function, Petitioner did not undergo a kidney biopsy. *Id*. Instead, after reviewing Petitioner's blood results, one of Petitioner's doctors theorized that Petitioner's kidney problem "could potentially be an acute post strep GN [glomerulonephritis]." *Id*. Despite this speculation, none of Petitioner's treating physicians diagnosed him with a streptococcus infection. *Id*.

Near the end of his hospital stay, a different doctor described Petitioner's chief complaint as "GBS 2/2 [secondary to] Tetanus vaccination." *Id*. at 5. Petitioner was discharged from the hospital to a rehabilitation facility on October 30, 2015. *Id*. at 4-5. In the discharge report, the discharging physician noted that Petitioner "had an allergy to tetanus toxoids and that the allergic reaction produced GBS."[2] *Id*. at 4.

II. The Petition and Procedural History

On August 29, 2016, Petitioner filed a petition seeking compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa–10-34,[3] alleging that his September 2015 Tdap vaccine caused him to develop GBS. ECF 1. In support of his Vaccine Act claim, Petitioner submitted medical records as well as expert reports from neurologist Yuval Shafrir to show that a Tdap vaccine can cause GBS and actually did so in this case. ECF 150 at 5, 7-8 (citing Pet. Ex. 20, ECF 66-1; Pet. Ex. 52, ECF 78-1; Pet. Ex. 58, ECF 90-1; Pet. Ex. 63, ECF 101-1, and Pet. Ex. 64, ECF 101-2). Specifically, in

[2] The Special Master noted that Petitioner's medical record from the Medical Center of Aurora contains several notes about Petitioner's allergic reaction to the tetanus vaccine. ECF 150 at 4 n.5. He also noted that multiple medical providers recognized that Petitioner developed GBS "following tetanus shot." *Id*.

[3] The National Vaccine Injury Compensation Program was established by the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (the Vaccine Act).

his initial expert report, Dr. Shafrir noted that the "[t]etanus vaccine is a known trigger for GBS," and set forth potential pathophysiological mechanisms by which tetanus toxoid could cause GBS. Pet. Ex. 20 at 14-17, ECF 66-1. In concluding that the Tdap vaccine caused Petitioner's GBS, Dr. Shafrir primarily relied on case reports of GBS following tetanus-containing vaccines, the temporal association between Petitioner's Tdap vaccination and the onset of his symptoms, and statements from Petitioner's treating physicians. *See* ECF 66-1.

Disputing causation, Respondent offered responsive reports from neuro-immunologist Thomas Leist. Resp't Ex. B, ECF 76-2; Resp't Ex. C, ECF 82-1; Resp't Ex. D, ECF 112-1. In his initial report, Dr. Leist disagreed with the proposition that the Tdap vaccine can cause GBS and in support relied on the 2012 report from the Institute of Medicine (IOM), which concluded that there is insufficient scientific evidence to accept or reject that tetanus-containing vaccines can cause GBS. *See* Resp't Ex. B at 4-5, ECF 76-2. Dr. Leist opined that Petitioner's GBS was not caused by Tdap and theorized that a group A streptococcal infection possibly caused Petitioner's GBS. *Id*. at 4, 6-7.

In April 2020, the Special Master introduced two exhibits (the Court Exhibits) into the record. *See* Court Ex. 1001, ECF 96-1; Court Ex. 1002, ECF 96-2. Both addressed recommendations by the Advisory Committee on Immunization Practices (ACIP), a federal advisory committee chartered to "provide expert external advice and guidance to the Director of [the Centers for Disease Control and Prevention (CDC)] on use of vaccines and related agents for the control of vaccine-preventable diseases." ECF 96-1 at 3. Court Exhibit 1001 is a CDC weekly report that compiled and summarized the recommendations from ACIP "regarding prevention and control of tetanus, diphtheria, and pertussis in the United States" in order to provide clinicians and public health providers with a comprehensive and up-to-date "resource."[4] *Id*. at 3-4. This April 2018 publication reflects the ACIP's recommendation that GBS occurring less than six weeks after receipt of a tetanus toxoid-containing vaccine warrants a precaution for subsequent administration of tetanus toxoid-containing vaccines. *Id*. at 6. Court Exhibit 1002,[5] a 2019 ACIP publication which outlines the ACIP's best practice guidelines for several vaccine-preventable diseases, likewise listed GBS less than six weeks after a previous dose of tetanus toxoid-containing vaccine as a precaution for the DT, Td, Tdap, and DTaP vaccinations. ECF 96-2 at 53, 57. The Special Master directed the parties to share the Court Exhibits with their

[4] Court Ex. 1001: Centers for Disease Control and Prevention, *Prevention of Pertussis, Tetanus, and Diphtheria with Vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 67 CDC MORBIDITY & MORTALITY WKLY. REP. 1 (Apr. 27, 2018), https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6702a1-H.pdf.

[5] Court Ex. 1002: EZEANOLUE E, ET AL., *General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices* (2019).

respective experts and, if desired, to submit supplemental expert reports addressing them. ECF 96. The Special Master also ordered the parties to submit briefs addressing the merits of Petitioner's claim to aid him in his determination of whether to hold an evidentiary hearing. ECF 93 at 1.

In May 2020, Petitioner submitted a supplemental report from Dr. Shafrir addressing the Court Exhibits. *See* ECF 101-1 (Ex. 63). He opined: "Court [E]xhibits 1001 and 1002 further support [Petitioner's] petition, as they reiterate the recognition of the relationship between Tdap vaccination that he received on September 21 [sic], 2015 and his [GBS]." *Id*. at 7. In June 2020, Petitioner filed his brief on entitlement. ECF 106.

In September 2020, Respondent filed his brief on entitlement, along with additional expert reports from Dr. Leist and Dr. Neal Halsey,[6] specifically addressing the Court Exhibits. ECF 112-114. Dr. Leist deemed the Court Exhibits consistent with a finding that evidence for a causal relationship between tetanus toxoid-containing vaccines and GBS is lacking and again opined that Petitioner did not suffer GBS as a result of his vaccination. ECF 112-1 (Ex. D) at 1-2, 4. Dr. Halsey likewise concluded that the inclusion of a precaution "is not evidence that CDC or the scientific or medical community has concluded that [tetanus toxoid-containing] vaccines can cause GBS." ECF 113-1 (Ex. E) at 5.

In October 2020, Petitioner filed a reply brief. ECF 116. After reviewing the parties' submissions, the Special Master scheduled an entitlement hearing. ECF 125 at 1. Two weeks before the scheduled hearing, the Special Master issued Findings of Fact to resolve inconsistencies in the medical records regarding the onset of Petitioner's GBS. ECF 132. The Special Master determined that onset occurred on September 28, 2015, ten days post-vaccination. *Id.* at 3.

During the May 2021 entitlement hearing, Petitioner and his wife testified about his health. *See, e.g.,* Hearing Tr. 11:6-16:3, 26:16-29:25, ECF 144. Dr. Shafrir testified for Petitioner, and Drs. Leist and Halsey testified for Respondent. *Id*. at 30:10-65:4, 90:25-139:16. Following the hearing, the Special Master issued an order directing the parties to brief whether the Court Exhibits constituted an admission by Respondent that tetanus-containing vaccines can cause GBS, and whether, as a matter of policy, Respondent should be allowed to offer expert testimony from Drs. Leist and Halsey to the contrary. ECF 139 at 1-2. In July 2021, Respondent filed his response to the order and argued that: (1) the CDC/ACIP guidelines reflected in the Court Exhibits do not represent an admission by the Secretary that tetanus toxoid-containing vaccines can cause GBS; and (2) it would be arbitrary and capricious for the Special Master to find that they are sufficient on their own to meet Petitioner's burden under the first prong of the causation test established in *Althen*

[6] Dr. Halsey is a pediatrician with subspecialty training in pediatric infectious diseases, epidemiology, preventive medicine, vaccines, and vaccine safety. ECF 113-1 (Ex. E) at 1.

v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). ECF 146 at 10. Petitioner filed his response three weeks later. ECF 147.

On January 27, 2022, the Special Master determined that Petitioner is entitled to compensation. *Mohamad v. Sec'y of Health & Hum. Servs*., No. 16-1075V, 2022 WL 711604, at *1 (Fed. Cl. Spec. Mstr. Jan. 27, 2022), ECF 150. As discussed in relevant part *infra*, the analysis section of the Special Master's 30-page entitlement ruling included: (1) an assessment of the credibility of the two original experts, Dr. Shafrir and Dr. Leist; (2) a discussion of each of the three *Althen* causation prongs; and (3) an analysis of whether an alternative factor caused Petitioner's GBS. *Id*. at 11-29.

As is relevant here, on the issue of general causation, the Special Master engaged in a chronological recitation of government publications that discuss, in part, a connection between a vaccine containing tetanus toxoid and GBS. *Id*. at 15-23. Specifically, the Special Master noted that, in 1994, the IOM published a comprehensive report addressing "whether childhood vaccines can cause adverse events," which found that "tetanus toxoid-containing vaccines *can* cause GBS based on a single case study, known as the Pollard-Selby case report."[7] *Id*. at 16. The Special Master went on to recognize that in 1996, the ACIP issued an update to its previously published recommendations pertaining to precautions, contraindications, side effects, and adverse reactions associated with vaccinations in which the ACIP found that the risk for GBS following administration of a tetanus vaccine was "extremely low." *Id*. at 18. The Special Master noted that, fifteen years later, in 2011, the ACIP again issued updated recommendations, and identified GBS less than six weeks after a previous dose of a tetanus toxoid-containing vaccine as a precaution against future tetanus vaccines. *Id*. at 19-20. The Special Master then noted how, in the following year, the IOM published a new report on vaccine safety in which it revisited the Pollard-Selby case report, retreated from its previous stance, and issued a neutral conclusion that neither favored nor rejected causation. *Id*. at 20, 24. Specifically, the IOM concluded that the "'evidence is inadequate to accept or reject a causal relationship between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and CIDP.'" *Id*. at 20. Finally, the Special Master described how, despite the IOM's updated position in 2012, the ACIP issued publications (i.e. the Court Exhibits) in 2018 and 2019 that continued to recognize a precaution against future tetanus vaccines for those who experienced GBS less than six weeks after receipt of a tetanus toxoid-containing vaccine. *Id*. at 21-23. After interpreting the meaning of the ongoing precaution, the Special Master found that the latest Court Exhibit "constitutes strong evidence that a tetanus vaccine can cause GBS in rare cases." *Id*. at 26.

[7] The Pollard-Selby case report followed a 42-year-old male laborer who had GBS on three separate occasions, each following receipt of a tetanus-toxoid containing vaccine. ECF 150 at 16.

In reaching this conclusion, the Special Master weighed expert testimony regarding the ACIP's recommendations and activities. *Id.* at 23-27. For example, Dr. Halsey testified that the ACIP likely failed to appreciate the significance of the 2012 IOM shift and that the ACIP's failure to update the recommendation regarding GBS and tetanus vaccines in the Court Exhibits represented an oversight. *Id*. at 24-25. He predicted that the ACIP would likely revise the recommendation in a future publication.[8] *Id*. at 27 n.27. Ultimately, because Dr. Halsey did not participate in the working group that led to the latest Court Exhibit and because evidence suggested the ACIP was aware of the 2012 IOM report, the Special Master declined to find Dr. Halsey's opinions on this point persuasive. *Id*. at 25.

After the parties spent nearly two years resolving Petitioner's damages, the Special Master awarded compensation in May 2024. ECF 256. On June 28, 2024, Respondent sought review of the Special Master's decision. ECF 258.

STANDARD OF REVIEW

Under the Vaccine Act, this Court has jurisdiction to review a special master's decision. 42 U.S.C. § 300aa–12(e)(2). In reviewing a special master's decision, this Court may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision, (B) set aside any of the findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa–12(e)(2)(A)-(C). The standards set forth in 42 U.S.C. § 300aa–12(e)(2)(B) "vary in application as well as degree of deference" as each "standard applies to a different aspect of the judgment." *Munn v. Sec'y of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). Findings of fact receive deferential review under the "arbitrary and capricious" standard; legal conclusions are reviewed under the "not in accordance with law" standard; and discretionary rulings are reviewed for "abuse of discretion." *Turner v. Sec'y of Health & Hum. Servs.,* 268 F.3d 1334, 1337 (Fed. Cir. 2001).

With respect to the arbitrary and capricious standard, "no uniform definition . . . has emerged," but it is "a highly deferential standard of review" such that "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and

[8] Respondent concedes that, despite Dr. Halsey's prediction, the ACIP has not updated its recommendations regarding tetanus-containing vaccines since its 2019 publication. ECF 259 at 12 n.7.

articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines v. Sec'y of Health & Hum. Servs*., 940 F.2d 1518, 1527-28 (Fed. Cir. 1991); *see also Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co*., 463 U.S. 29, 43 (1983) (a decision is arbitrary and capricious only if it is "so implausible that it could not be ascribed to a difference in view"). "The arbitrary and capricious standard of review is difficult for an appellant to satisfy with respect to any issue, but particularly with respect to an issue that turns on the weighing of evidence by the trier of fact." *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1360 (Fed. Cir. 2000). That is because it is not for the courts to "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011) (citing *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1349 (Fed. Cir. 2010)).

The "not in accordance with law" standard, on the other hand, is applied without deference to legal determinations, such as "[w]hether the special master applied the appropriate standard of causation . . . ." *Deribeaux v. Sec'y of Health & Hum. Servs*., 717 F.3d 1363, 1366 (Fed. Cir. 2013). Lastly, the abuse of discretion standard applies to the special master's discretionary rulings, such as evidentiary determinations regarding the qualification of experts and the admissibility of their testimony. *Piscopo v. Sec'y of Health & Hum. Servs*., 66 Fed. Cl. 49, 53 (2005). Determinations subject to review for abuse of discretion must be sustained unless "manifestly erroneous." *Id*.; *see also Milmark Servs., Inc. v. United States*, 731 F.2d 855, 860 (Fed. Cir. 1984).

DISCUSSION

Respondent raises two objections to the Special Master's finding of entitlement and subsequent compensation award. First, he argues that the Special Master impermissibly shifted the burden of proof to the Secretary to prove he had not conceded prong 1 of the *Althen* causation test, rather than properly placing the burden on Petitioner to affirmatively prove a medical theory. ECF 258 at 1; ECF 259 at 6. Second, Respondent argues that the Special Master erred in finding that Respondent conceded *Althen* prong 1 and "ignored other important record evidence." ECF 258 at 1; ECF 259 at 6, 17. Respondent raises no objection to the Special Master's application of the remaining *Althen* prongs.

I. Legal Framework

Under the Vaccine Act, petitioners bear the burden of proving that a vaccine caused an injury or death. 42 U.S.C. § 300aa–13(a)(1). There are two methods by which a petitioner may establish causation and thus eligibility for an award of compensation. *Munn*, 970 F.2d at 865. Through the first method, a petitioner may demonstrate causation through a statutorily prescribed presumption by showing that the alleged injury meets the criteria

listed on the Vaccine Injury Table, as set forth in 42 U.S.C. § 300aa–14 and 42 C.F.R. § 100.3. *Id.* The Table identifies the covered vaccines, the corresponding injuries, and the time period after vaccination in which the particular injuries must occur. 42 C.F.R. § 100.3. "[I]f a petitioner can establish that [he] received a listed vaccine and experienced such symptoms or injuries within the specified timeframes, [he] has met [his] prima facie burden to prove that the vaccine caused [his] injuries." *de Bazan v. Sec'y of Health & Hum. Servs*., 539 F.3d 1347, 1351 (Fed. Cir. 2008). Alternatively, and most relevant here, if a petitioner suffered an "off-Table injury," he must prove "causation-in-fact" by a preponderance of the evidence. *See* 42 U.S.C. §§ 300aa–11(c)(1)(C)(ii), 13(a)(1); *see also Broekelschen*, 618 F.3d at 1341-42. The Federal Circuit has "interpreted the 'preponderance of the evidence' standard referred to in the Vaccine Act as one of proof by a simple preponderance, of 'more probable than not' causation." *Althen*, 418 F.3d at 1279. Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). "Once causation is established, the petitioner is entitled to compensation unless the Government can show by a preponderance of the evidence that the injury is due to factors unrelated to the vaccine, i.e., an alternative cause." *Porter*, 663 F.3d at 1249.

In this case, Petitioner alleged that a Tdap vaccination caused him to suffer GBS. ECF 1 at 1. GBS is not a Table injury for the Tdap vaccine. *See* 42 C.F.R. § 100.3(a). Petitioner therefore could not claim a presumption of causation, and instead was required to affirmatively prove causation-in-fact. Under the test articulated by the Federal Circuit in *Althen*, the test for proving causation-in-fact requires a showing of: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a proximate temporal relationship between vaccination and injury. 418 F.3d at 1278.

II. The Special Master Did Not Improperly Shift the Burden of Proof on *Althen* Prong 1 nor Exceed His Legal Authority.

Respondent argues that the Special Master acted contrary to law by shifting the burden to the Secretary of Health and Human Services to prove that he had not conceded prong 1 of the *Althen* causation test, rather than properly placing the burden on Petitioner to affirmatively prove a medical theory causally connecting the vaccination and injury. ECF 258 at 1; ECF 259 at 15-16. Specifically, Respondent takes issue with the Special Master's introduction of the Court Exhibits and argues he impermissibly "placed the burden on *respondent* to disprove [his] *own* interpretation of that evidence," effectively granting petitioners a legal presumption of causation. ECF 259 at 15-16. When faced with such a contention, the Court of Federal Claims reviews the Special Master's application of the law *de novo*. *Rodriguez v. Sec'y of Health & Hum. Servs.*, 632 F.3d 1381, 1384 (Fed. Cir. 2011) ("'Not in accordance with the law' refers to the application of the wrong legal standard, and the application of the law is reviewed *de novo.*").

In this case, the Special Master repeatedly cited the correct burden of proof. *See*, e.g., ECF 150 at 10. He acknowledged that petitioners are generally required to establish their cases by a preponderance of the evidence, and he specifically recognized that

petitioners pursuing an off-Table injury bear the burden of demonstrating each of the *Althen* prongs by preponderant evidence. *Id*. With respect to Petitioner specifically, he repeatedly emphasized that Petitioner bore (and carried) the initial burden of proof. For example, he noted that "[Petitioner] carried his burden of proof," *id*. at 1, that the evidence before him was "sufficiently robust that it carries [P]etitioner's burden with respect to general causation," *id*. at 26, and that "[t]he lack of testing does not prevent [Petitioner] from meeting his burden of proof . . . ." *Id*. at 29. Indeed, even in the language Respondent cites for the proposition that it is "clear on which party the Special Master placed the burden," ECF 259 at 16 ("Mr. Mohamad cannot be expected to bear a higher burden than the Secretary . . . ."), the Special Master made clear that, regardless of how high or low the evidentiary burden, the onus was on *Petitioner* to meet it.

Respondent next takes issue with the fact that the relevant evidence was submitted by the Special Master, not the Petitioner. According to Respondent, the Special Master "relied *solely* on evidence *he* filed into the record," *id*. at 15 (first emphasis added), which happens to be written materials created and distributed by the Government. But this challenge ignores the unique inquisitorial role special masters play in Vaccine Act cases, in which the "permissible scope of the special master's inquiry is virtually unlimited." *Whitecotton v. Sec'y of Health & Hum. Servs.*, 81 F.3d 1099, 1108 (Fed. Cir. 1996) ("Congress desired the special masters to have very wide discretion with respect to the evidence they would consider and the weight to be assigned that evidence."). Notably, Respondent does not challenge the admissibility of the Court Exhibits, *see* ECF 146 at 4-5, and he offers no authority contesting the Special Master's ability to consider material not introduced by the parties. *See Hines*, 940 F.2d at 1526 (finding no error where the special master took judicial notice of a medical textbook that was not part of the record at hearing); *see also Massachusetts v. Westcott*, 431 U.S. 322, 323 n.2 (1977) (public records "may be judicially noticed"). Nor does Respondent cite any authority for the proposition that evidence introduced into the record cannot be used for any purpose. Instead, without invoking any prohibiting authority, Respondent complains that the Special Master relied on evidence that he himself introduced to find that Petitioner met his burden on *Althen* prong 1. The trouble with this approach is that it ignores the Vaccine Act's statutory instruction for the Special Master to consider "the record as a whole," which in this case includes "the Court Exhibits [the Special Master] himself filed." *See* 42 U.S.C. § 300aa–13(a)(1) (requiring fact findings to be based "on the record as a whole").

Concerned by the prospect of special masters finding petitioners met their burden of proof by relying on record evidence not supplied by petitioners themselves, Respondent argues that, by relying on the Court Exhibits, the Special Master improperly granted "a legal presumption of causation" linking tetanus toxoid-containing vaccines with GBS. *See* ECF 259 at 16. According to Respondent:

> If the Special Master's entitlement ruling in this case is upheld, then no petitioner in any future case alleging GBS due to a tetanus-containing vaccine would need to produce *any*

> evidence addressing *Althen* prong one, which is tantamount to petitioners being granted a legal presumption of causation in such cases. In other words, the Special Master effectively made GBS a presumptive injury for the Tdap vaccine – i.e., a Table injury.

Id. This argument fails. It does not follow that just because the Special Master considered evidence he himself filed in the record of this case (which again, Respondent did not challenge on admission), petitioners in all future Tdap-GBS cases are granted a presumption of causation. Instead, any findings of causation in those cases will turn on the evidence on record *in those cases*. Such records may or may not include evidence of the Court Exhibits along with any other evidence filed by the parties. The Special Master recognized as much, and noted that if the evidence differs a different result might follow:

> If Dr. Halsey's prediction that the ACIP revises the Secretary's guidance comes true, then the evidence will be different. The parties might also present different evidence in the form of testimony from immunologists, epidemiologists, and/or people with first-hand knowledge of the creation of the 2019 Best Practices. Different evidence in any hypothetical future case might yield a different result.

ECF 150 at 27 n.27. Such acknowledgment is hardly indicative of the grant of a legal presumption of causation; instead, it demonstrates an expectation that, as required by statute, special masters consider "the record as a whole." *See* 42 U.S.C. § 300aa–13(a)(1).

Notably, since the Special Master issued the entitlement ruling in this case, Respondent's fear of special masters applying a legal presumption has not come to pass. Other special masters have considered petitions alleging a Tdap-GBS association and decided them based on the evidence before them. *See, e.g*., *K.A. v. Sec'y Health & Hum. Servs*., No. 16-969V, 2022 WL 20213037, at *23, 25 (Fed. Cl. Spec. Mstr. Apr. 18, 2022), *review denied*, *decision aff'd*, 164 Fed. Cl. 98 (2022), *aff'd*, No. 2023-1315, 2024 WL 2012526 (Fed. Cir. May 7, 2024) (distinguishing *Mohamad* in part because almost all of the publications it evaluated were not offered as evidence in that case and recognizing that "the outcome in such cases is mostly a function of the evidence before the special master, with no clear trend one way or the other"); *see also Harris v Sec'y of Health & Hum. Servs*., No. 18-944V, 2023 WL 2583393, at *22-27 (Fed. Cl. Feb. 21, 2023) (noting the Court Exhibits were not filed in that case and finding other adequate evidence to demonstrate that Tdap vaccines can cause GBS). !

Finally, in resolving this issue, the Court notes that Respondent's argument is predicated on a faulty premise, specifically that in finding Petitioner satisfied *Althen* prong 1, "the Special Master . . . relied *solely* on evidence *he* filed into the record." ECF 259 at 15 (first emphasis added). This statement mischaracterizes the Special Master's actions. It

is true that the Special Master's analysis on the first *Althen* prong afforded great weight to his interpretation of the Court Exhibits. However, as described in more detail below, the Special Master also considered the whole history of reports and actions taken under the authority of the Secretary, and emphasized evidence of *prior* post-vaccination demyelination, suggesting proof of "rechallenge," a pattern of recurrence that can demonstrate that an exposure is causing an adverse reaction. *See Capizzano v. Sec'y of Health & Hum. Servs*., 440 F.3d 1317, 1322 (Fed. Cir. 2006) (defining rechallenge). Further, in reaching his ultimate conclusion that Petitioner carried his burden of proof, the Special Master wrote: "[t]he Secretary's documents show that a tetanus vaccine can cause GBS. This evidence *plus the reports from doctors who treated Mr. Mohamad* constitute preponderant evidence." ECF 150 at 1 (emphasis added). The Special Master went on to specifically note that, in resolving *Althen* prong 1, he relied on statements from Petitioner's doctors: "[Petitioner]'s treating doctors' statements that a tetanus vaccine caused his GBS also imply that a tetanus vaccine can cause GBS generally. As such, these statements from treating doctors are also relevant to the prong 1 discussion above." ECF 150 at 29 (citing *Caves v. Sec'y of Health & Hum. Servs*., 100 Fed. Cl. 119, 136-37 (2011), *aff'd without opinion*, 463 F. App'x 932 (Fed. Cir. 2012)). In light of this other evidence, it is simply not accurate to say that "the Special Master relied *solely* on evidence *he* filed into the record" or that he "arbitrarily began and ended his analysis with the Court Exhibits." ECF 259 at 15, 18. As such, the Court cannot conclude that the Special Master improperly shifted the burden of proof nor that he exceeded his legal authority.

III. The Special Master's Evaluation of the Evidence Was Not Arbitrary and Capricious.

Next, Respondent argues that the Special Master's finding that Respondent conceded *Althen* prong 1 was based on an arbitrary and capricious evaluation of the evidence and that, in reaching that finding, he "ignored other important record evidence and gave undue weight to his own unsupported interpretation of Court [E]xhibits." *Id*. at 17.

The crux of this challenge is that the Special Master improperly weighed the evidence before him. But it is not for this Court to "reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter*, 663 F.3d at 1249. It is simply "not our role to 'second guess the Special Master[']s fact-intensive conclusions' particularly in cases 'in which the medical evidence of causation is in dispute.'" *Id*. (quoting *Hodges v. Sec'y of Health & Hum. Servs*., 9 F.3d 958, 961 (Fed. Cir. 1993)). Instead, special masters are entitled to "the special statutory deference in fact-finding normally reserved for specialized agencies." *Munn*, 970 F.2d at 871. This is because "Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims." *Hodges*, 9 F.3d at 961. Accordingly, if the Special Master's

findings of fact are "based on evidence in the record that [is] not wholly implausible," the Court is compelled to uphold that finding. *Cedillo v. Sec'y of Health and Hum. Servs.*, 617 F.3d. 1328, 1338 (Fed. Cir. 2010).

Under *Althen* prong 1, Petitioner was required to demonstrate by a preponderance of the evidence a medical theory causally connecting the Tdap vaccine and GBS. *Althen*, 418 F.3d at 1278. Put differently, Petitioner was required to show that the vaccine *can cause* the type of injury alleged. *See Capizzano*, 440 F.3d 1326 (finding the first prong of *Althen* satisfied by the finding that the hepatitis B vaccine can cause rheumatoid arthritis). While "[a] petitioner must provide a reputable medical or scientific explanation that pertains specifically to petitioner's case … the explanation need only be 'legally probable, not medically or scientifically certain.'" *Moberly v. Sec'y of Health & Hum. Servs*., 592 F.3d 1315, 1322 (Fed. Cir. 2010). Petitioners may satisfy this prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Capizzano*, 440 F.3d at 1325-26.

In this case, the Special Master devoted thirteen full pages of his analysis to the first *Althen* prong. *See* ECF 150 at 14-27. His ruling reveals a thorough and careful evaluation of the evidence. *Id.* After discounting the opinions of Drs. Shafrir and Leist, the two original experts, due to credibility concerns, he: (1) discussed at length the demonstrated evolution of the Government's published scientific/medical conclusions about tetanus-GBS causality, as well as some of the underlying studies it relied upon; (2) noted the Vaccine Program's historical treatment of the issue; and (3) weighed expert testimony regarding the ACIP's recommendations and activities. *Id*. at 15-26. Ultimately, he concluded that the Government's most recent publication "constitutes strong evidence that a tetanus vaccine can cause GBS in rare cases" and is "sufficiently robust [such] that it carries Petitioner's burden with respect to general causation." *Id*. at 26.

This finding was not arbitrary and capricious. As discussed at length by the Special Master, the Court Exhibits contain evidence that as late as 2019 the ACIP offered as a "precaution" that Tdap was to be carefully considered for individuals who previously had experienced GBS within six weeks of a tetanus toxoid-containing vaccine.[9] ECF 150 at 26. Although a "precaution" is not as strong as a "contraindication," it is still evidence of an association between GBS, tetanus toxoid-containing vaccines, and the possibility of a serious adverse reaction. *See* ECF 96-2 at 51 (defining "precaution" as "a condition in a

[9] The parties agree that the ACIP has not updated its recommendations concerning tetanus toxoid-containing vaccines since its 2019 publication. *See* ECF 259 at 12 n.7; ECF 261 at 28.

recipient that might increase the risk for a serious adverse reaction, might cause diagnostic confusion, or might compromise the ability of the vaccine to produce immunity").[10]

To be sure, the Court Exhibits do not themselves specify that one possible adverse reaction is a recurrence of GBS. However, support for this finding is in the record. Specifically, in a 1996 update to previously published ACIP recommendations pertaining to precautions, contraindications, side effects, and adverse reactions associated with vaccinations, the ACIP noted that "[p]ersons who have a history of GBS associated with a particular vaccine may be at increased risk for recurrent GBS after subsequent doses of that vaccine." Resp't Ex. E, Tab 3 at 14, ECF 113-4. After finding that "the risk for GBS after administration of tetanus toxoid is very low," the ACIP identified GBS as a precaution in all but name for tetanus vaccination due to the possibility of recurrence. *Id.* It did so, "[b]ecause tetanus vaccination has been associated rarely with recurrence of GBS, [and] the decision to administer additional doses of tetanus-toxoid-containing vaccine to persons who have had GBS within 6 weeks after receiving tetanus toxoid should be based on the benefits of subsequent vaccination and the risk for recurrence of GBS."[11] *Id*. The Special Master discussed the 1996 update at length in his entitlement ruling, ECF 150 at 17-18, and read it alongside Court Exhibit 1002 to interpret the significance of—and rationale for—the ongoing precaution. *Id*. at 26. Given the lack of a stated explanation for the precaution in the Court Exhibits, the Court will not fault the Special Master for considering the 1996 update in conjunction with the Court Exhibits as it provides context for why the ACIP continues to identify GBS less than six weeks after a previous dose of tetanus vaccine as a precaution against future tetanus vaccines. Accordingly, because the Court finds that the Special Master's finding that "a tetanus vaccine can cause GBS in rare cases" is supported by evidence in the record that is "not wholly implausible," the Court will not disturb the Special Master's finding. *Cedillo,* 617 F.3d. at 1338.

The Court recognizes that much of Respondent's concern is with the fact the Special Master allegedly found the Secretary *conceded* the first *Althen* prong. It is true that the Special Master's analysis primarily rested on finding that "the Secretary acknowledged the low risk that in rare cases a tetanus vaccine can cause GBS by making a prior occurrence

[10] On September 11, 2024, the Court ordered supplemental briefing regarding the significance of the fact Petitioner did not previously develop GBS within six weeks of a prior tetanus vaccine, as required for the precaution to apply to him at the time of his September 2015 Tdap vaccination. ECF 263 at 1. Upon consideration of the parties' briefs (ECF 264, ECF 265) as well as further review of the "challenge-rechallenge" paradigm, the Court is satisfied that evidence of "rechallenge" in other injectees can constitute proof of general causality under *Althen* prong 1. *See Capizzano*, 440 F.3d at 1326 (Fed. Cir. 2006) (affirming decision in *Capizzano v. Sec'y of Health & Hum. Servs*., No. 00-759, 2004 WL 1399178, at * 16 (Jun. 8, 2004), which concluded that the "[C]ourt need not determine an exact mechanism for which Hepatitis B occurs in rechallenge cases *or in any other cases* where a hepatitis B vaccination allegedly caused [rheumatoid arthritis]" given the IOM's position that "rechallenge is tantamount to causation")).

[11] Although the 1996 update did not expressly characterize the ACIP's recommendation as a precaution, Dr. Halsey testified that the ACIP "listed it as a precaution" in his testimony regarding the 1996 update. Hearing Tr. 232:20-25, ECF 145.

of GBS in temporal relationship with a tetanus vaccine a precaution." ECF 150 at 27. However, the Court finds no fault with the Special Master recognizing the source of the evidence before him. The Court Exhibits, which acknowledge a continuing concern over administering doses of a tetanus toxoid-containing vaccine to persons who previously suffered GBS within six weeks of receiving a prior dose, *were* created under the authority of the Secretary.[12] Recognizing this fact is not improper. Nor does such acknowledgment serve as an indication that the Special Master's decision turned solely on whether the Court Exhibits constituted an admission. Although the Special Master once ordered briefing on the issue of whether the Court Exhibits constituted an admission by a party-opponent pursuant to Rule 801(d)(2) of the Federal Rules of Evidence, ECF 139, he "apparently abandoned any reliance on Rule 801(d)(2) since it was not addressed in the Decision," as conceded by Respondent, and he at no point referred to the Court Exhibits as an admission or concession. ECF 259 at 15-16 n.10; *see generally* ECF 150. Accordingly, the Court interprets the Special Master's language for what it is—recognition of publications written under the authority of the Secretary that the Special Master interpreted as demonstrating some association between a tetanus vaccine and GBS.

Respondent also contends that the Special Master "ignored other important record evidence." ECF 259 at 17. Specifically, Respondent argues that the Special Master's analysis included no discussion of the available epidemiological studies, some of which were discussed in the IOM's 2012 report and that served as the basis of subsequent special master decisions rejecting a causal association between tetanus-containing vaccines and GBS. *Id*. at 17-18. Respondent argues that "at a minimum, [the Special Master] should have explained why that evidence was not deserving of more weight in his causation analysis." *Id*. at 18. Respondent also argues that, in evaluating the persuasiveness of Dr. Halsey's testimony, the Special Master failed to mention evidence of correspondence and discussions between Dr. Halsey and ACIP members pertaining to ACIP's recommendation regarding GBS and Tdap. *Id*. at 18. In Respondent's view, these communications show that Dr. Halsey was not engaging in "rank speculation" as to ACIP's intentions. *Id*.

This argument fails for a simple reason: the Court "generally presume[s] that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision." *Moriarty v. Sec'y of Health & Hum. Servs*., 844 F.3d 1322, 1328 (Fed. Cir. 2016). Respondent cites no authority—and the Court is aware of none—for the proposition that a special master is required to explicitly address every piece of record evidence. Indeed, this Court has previously recognized that a special master is "not required to discuss every piece of evidence or testimony in [his or] her decision."

[12] The Court Exhibits involve discussion of recommendations by ACIP, which was established by the Secretary under Section 222 of the Public Health Service Act, 42 U.S.C. § 217a. ACIP's members are selected by the Secretary to advise the Director of the CDC. *See* 96-1 at 3; https://www.cdc.gov/acip/about/acip-charter.html (last accessed Oct. 16, 2024). Once ACIP's recommendations are reviewed and approved by the CDC Director, recommendations are published in the CDC's *Morbidity and Mortality Weekly Report*, which represents the official CDC recommendations for immunizations of the U.S. population. *Id*.

Simanski v. Sec'y of Health and Hum. Servs., 115 Fed. Cl. 407, 436 (2014), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015) (alteration in original).

Moreover, in this case, the supposedly "ignored" evidence is of little consequence. First, with respect to the Special Master's silence as to epidemiological studies that were discussed in the IOM's 2012 report and served as the basis for subsequent special master decisions, the Court fails to understand why the Special Master would need to address such studies when he discussed at length the IOM report that drew from those studies. Put another way, why would the Special Master need to discuss the underlying studies when he scrutinized the conclusion that flowed from those studies?

Second, with respect to the Special Master's supposed failure to mention Dr. Halsey's correspondence and discussions with ACIP members when evaluating the persuasiveness of Dr. Halsey's testimony, the Court notes that the Special Master acknowledged Dr. Halsey's "first-hand knowledge" and "insights into the process leading to the production of the documents." ECF 150 at 24. He explicitly noted that he did not readily dismiss Dr. Halsey's opinion. *Id*. at 26. Nevertheless, the Special Master still articulated multiple reasons for deeming unpersuasive Dr. Halsey's assertion that the ACIP did not consider modifying the recommendation for GBS. *Id*. at 25-26. As such, even if the Special Master had fully credited Dr. Halsey's email correspondence and other communications with ACIP members in the manner Respondent wishes he had, the Special Master still would have had other reasons for finding Dr. Halsey's opinions unpersuasive.

For the foregoing reasons, the Court finds the Special Master did not engage in an arbitrary and capricious evaluation of the evidence. Instead, he thoughtfully "considered the relevant evidence of record, dr[ew] plausible inferences and articulated a rational basis for the decision." *Hines*, 940 F.2d at 1527-28.

CONCLUSION

In this case, the Special Master applied the appropriate standard, engaged in a lengthy review of Government publications that discuss, in part, a connection between a vaccine containing tetanus toxoid and GBS, and articulated a rational basis for finding that Petitioner met his burden in demonstrating *Althen* prong 1. Accordingly, Respondent's Motion for Review (ECF 258) is **DENIED** and the Special Master's Decision is **SUSTAINED**. The Clerk of the Court is directed to enter judgment accordingly.

IT IS SO ORDERED.

PHILIP S. HADJI
Judge